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TITLE: Cognitions, Decisions and Behaviors Related to Successful Adjustment among Individuals with SCI: A Qualitative Examination of Military and Nonmilitary Personnel

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14. ABSTRACT

This project is designed to find out how successful adjustment happens after SCI. Successful individuals will be identified through a survey. Those individuals (military and not) will be then be recruited to take part in interviews to help identify key factors in successful adjustment after SCI.

The research project has not yet begun recruiting subjects. The project received initial approval for the study on 01 OCT 13. The survey phase of the project will begin with the University of Michigan and expand to the other sites once they are authorized to begin.

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Introduction

This project is designed to find out how successful adjustment happens after SCI. We will start by identifying "successful" and resilient individuals with SCI via a mail survey to the known population of individuals with SCI served by the associated project sites (phase 1). We will then recruit a stratified sample of successful individuals and use qualitative techniques to gather details from them about their lives and experiences (phase 2). We will focus on finding out about the thoughts they had, the decisions they made and the behaviors they performed in the first few years after injury, as well as what factors influenced these. By illuminating the process of positive adjustment and successful self-regulation after SCI and articulating specific and concrete cognitions, decisions and behaviors, this project will provide foundational information to enhance existing intervention and develop new assessments and programs.

Body

The research study team has made the following progress on the Statement of Work tasks during Year 1 of this project:

Task 1: Maintain regular contact with Funding agency and Advisory Board

Both Dr. Meade and Mr. Trumpower have been in regular contact with DoD personnel, particular Ms. Lori Walthers. Contact with our Advisory Board has occurred over the phone, through e-mail and in person.

1a. Attend and participate in program review meetings in Washington DC area (years 1 and 3)

- The meeting in Y1 was cancelled.

1b. Attend and participate in DoD Sponsored scientific meeting

- PI was not able to attend the recent meeting due to the short amount of notice given. Please notify the research study team as soon as possible regarding the date of the next scientific meeting.

1c. Complete all grant related progress reports

- All progress reports have been completed and submitted.

Task 2: Complete all necessary regulatory review and approval processes for research involving human subjects (months 0 to 6; month 13; month 24)

This project involves two phases (mail survey and qualitative interviews) which have been submitted as two separate studies to the University of Michigan IRB. In addition, the mail survey (phase one) study has been subjmitted to the IRB at the Rehabilitation Institute of Michigan and the Ann Arbor VA. While the DoD considers the Paralyzed Veterans of Michigan (PVA) as its own site, it does not have an IRB and so is included under the University of Michigan IRB. As approvals have been received from a site, the paperwork has been submitted to DoD scientific officer.

- We submitted the IRB for the phase one study (mail survey) to the University of Michigan IRB on 20 SEP 12.
- We submitted the IRB for the phase two study (qualitative interviews) to the University of Michigan IRB on 21 SEP 12.
- The University of Michigan IRB initially approved the study on 19 FEB 13 and approved the latest amendment on 26 SEP 13.
- We submitted the paperwork for to the DoD Human Subjects Review committee on _06 MAR 13 (phase 1) and 26 APR 13 (phase 2).
- On 03 JUL 13, RIM received authorization to proceed with submitting an application for research to Wayne State University. The application was submitted on 15 JUL 13. After contingencies were satisfied, approval was granted on 20 SEP 13. The research site study team is awaiting receipt of signed documents before forwarding them to University of Michigan and DoD.
- The VA IRB reviewed the application on 12 SEP 13 and returned to the research study team for revisions on 26 SEP 13.
- We received initial approval for the phase 1 study from the DoD on 01 OCT 13.

Task 3: Finalize Screening Survey (months 1-4)

3a: Meet with advisory board to finalize questions / scales needed to identify individuals with SCI with successful adjustment.

- The study staff held an advisory board meeting in April 2013 to finalize the mailing survey.

3b. Design postcards and layout of survey to be easy to understand and complete

- The postcard design and layout have been created.
- The research study team has waited to print the postcards and other materials until final approval was given from the local site and the DoD.

Task 4: Conduct Screening Survey (months 6 to 12)

4a: Develop or Review and finalize mailing lists at all sites

- Recent approval from the DoD for the University of Michigan and Michigan Paralyzed Veterans association means that the recruitment list can now be developed. We could not access the PHI for this purpose until after we received IRB approval. A request to the UM Honest Broker was submitted on 09 OCT 13.
- RIM is now awaiting DoD approval in order to create its mailing list.
- The development of the mailing list for the Ann Arbor VA, to include individuals with SCI in VSION 11, will occur following VA IRB and DoD Human Subjects approval.

4b: Print / copy postcards, envelopes and survey instruments

- Printing process has begun for University of Michigan materials (October 2013).
- Printing for other sites will occur once their approvals are received.

4c. Establish web survey

- The web survey is completed and is ready for data collection.

*Subtasks 4d to 4g will be completed immediately following completion of subtask 4b.

4d: Create / compile survey packages for distribution to various sites
- Expected to occur for University of Michigan in November 2013.
- Will occur for AAVA and RIM sites following approvals.

4e. Where possible (UM, RIM, AAVA), track survey number by matching it with name on mailing / recruitment list

4f. Conduct 4-part mailing – notification post card; survey; reminder post-card; second survey
- Delayed at all sites because of delays in regulatory approvals.

4g. Track and enter information from returned surveys into REDCap database (UM Research assistant)

- Please note that REDCap will no longer be used for data storage. All data will be stored in the Qualtrics database. This step was taken to simplify data storage by eliminating the need to merge databases.

<u>Task 5: Review and analyze data (months 9 to 12)</u>

*We have not started to collect data. We will not be able to accomplish Task 5 until data has been collected.

5a. Review of data by study investigators

5b. Classification of respondents into categories based on military background, level of resources, and time since injury as well as based on responses of adjustment measures.

5c. Extraction of data into SPSS for analysis and dissemination

Task 6: Finalize semi-structured interview and assessments for in-person interviews (Months 9 to 12)

6a. Meet with advisory board to finalize content and focus of interview

- The advisory board meeting to complete this task will occur in the few months.

6b. Practice / pilot semi-structured interview to ensure clarity and comprehensiveness

- This step will be completed after the interview content and focus has been finalized

Key Research Accomplishments

The sites have gotten together and established a joint vision for the project and anticipated outcomes. In the process, the Great Lakes SCI Collaborative Network has been developed and will hopefully continue to expand to include other organizations. The research project received approval from the DoD on 01 OCT 13 and University of Michigan on 26 SEP 13. An advisory board meeting was held to review the purposes, intents, and materials of the study with community stakeholders and collaborating sites.

Reportable Outcomes

Data collection has not begun. Surveys will be sent out in Y2Q1.

Conclusion

The first year of the project has been centered on attaining regulatory approval and finalizing all materials. The IRB / HRPO review process is a thorough and diligent task to ensure the protection of the human subjects. Now that the project has been approved to commence data collection at the University of Michigan, the project can begin to move forward. The progress with VA site approval has been deliberate due to particular requirements that are germane to performing research with the VA.

Year 2 of the project will allow for data collection to begin. The surveys will go out in large waves. We should start to see surveys returning to us pretty quickly after they are sent out. Successful individuals with SCI will be identified and individual interviews will begin to be scheduled soon after data collection for a site has been completed.

References

None

Appendices

Not applicable